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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/602,691	06/20/2003	Jean-Pierre Sommadossi	06171.IDX 1007 CON1	1388

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KING & SPALDING LLP  
1180 PEACHTREE STREET  
ATLANTA, GA 30309

EXAMINER
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MCINTOSH III, TRAVISS C

ART UNIT	PAPER NUMBER
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1623

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02/26/2008

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/602,691	<b>Applicant(s)</b> SOMMADOSSI ET AL.	
	<b>Examiner</b> TRAVISS C. MCINTOSH III	<b>Art Unit</b> 1623	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 31 October 2007.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 130-160 is/are pending in the application.
- 4a) Of the above claim(s) 153-157 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 130-152 and 158-160 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                       | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>11/7/07</u> .   | 6) <input type="checkbox"/> Other: _____                          |

### **DETAILED ACTION**

The Amendment filed 10/31/2007 has been received, entered into the record, and carefully considered. The following information provided in the amendment affects the instant application by:

Claims 153-160 have been added

Claims 1-129 have been canceled.

Remarks drawn to rejections of Office Action mailed 8/22/2007 include:

Double Patenting Rejections: which has been maintained for reasons of record.

An action on the merits of claims 130-160 is contained herein below. The text of those sections of Title 35, US Code which are not included in this action can be found in a prior Office action.

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 10/31/07 has been entered.

Newly submitted claims 153-157 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: these claims are drawn to a different statutory class of invention; products versus methods of use.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 153-157 withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

### ***Claim Objections***

Claim 144 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. It is unclear how claim 144 limits claim 130 as the  $\beta$ -D-2'-methyl-ribofuranosyl nucleoside is the only thing capable of being administered in claim 130.

Applicant is advised that should claim 131 be found allowable, claim 147 will be objected to under 37 CFR 1.75 as being a substantial duplicate thereof. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k). Claim 147 limits claim 144 in the same manner as claim 131 limits 130. Since claim 144 is not seen to limit claim 130, as set forth supra, claim 147 is seen to be the same as claim 131.

Applicant is advised that should claim 132 be found allowable, claim 150 will be objected to under 37 CFR 1.75 as being a substantial duplicate thereof. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other

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as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k). Claim 150 limits claim 144 in the same manner as claim 132 limits 130. Since claim 144 is not seen to limit claim 130, as set forth supra, claim 150 is seen to be the same as claim 132.

Claims 158-160 are objected to for depending from a withdrawn claim. It is noted the examiner is interpreting these claims as treating HCV with the compound of claim 153 even though the compound claims are withdrawn.

### ***Double Patenting***

The provisional rejection of claims 130, 132-146, and 150-152 on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 2-3, 8-17, and 19-67 of copending Application No. 11/005,466 is maintained for reasons of record. Although the conflicting claims are not identical, they are not patentably distinct from each other because both applications are drawn to methods of treating HCV by administering purine 2'-methyl-ribofuranosyl nucleosides and optionally in combination with another antiviral agent thus using the same forms of compositions in the same patients. It is obvious that the instant application and the '466 application are substantially overlapping.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

It is noted applicants argued that since the only rejections left are provisional rejections, then the case should be issued according to MPEP 804, subsection I.B. However, since there are still pending rejections, this is not found persuasive.

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The provisional rejection of claims 130-131 and 137-149 on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 11, 12, 17-25, and 43-65 of copending Application No. 10/609,298 is maintained for reasons of record. Newly added claims 158-160 are rejected for the same reasons. Although the conflicting claims are not identical, they are not patentably distinct from each other because both applications are drawn to methods of treating HCV by administering pyrimidine 2'-methyl-ribofuranosyl nucleosides using the same forms of compositions in the same patients. It is obvious that the instant application and the '298 application are substantially overlapping.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

It is noted applicants argued that since the only rejections left are provisional rejections, then the case should be issued according to MPEP 804, subsection I.B. However, since there are still pending rejections, this is not found persuasive.

The provisional rejection of claims 130-131 and 137-149 on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 2-3, 8-17, and 19-52 of copending Application No. 11/005,440 is maintained for reasons of record. Newly added claims 158-160 are rejected for the same reasons. Although the conflicting claims are not identical, they are not patentably distinct from each other because both applications are drawn to methods of treating HCV by administering pyrimidine 2'-methyl-ribofuranosyl nucleosides using the same forms of compositions in the same patients. It is obvious that the instant application and the '440 application are substantially overlapping.

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This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

It is noted applicants argued that since the only rejections left are provisional rejections, then the case should be issued according to MPEP 804, subsection I.B. However, since there are still pending rejections, this is not found persuasive.

The provisional rejection of claims 130-131 and 133-149 on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 2-17 and 19-66 of copending Application No. 11/005,443 is maintained for reasons of record. Newly added claims 158-160 are rejected for the same reasons. Although the conflicting claims are not identical, they are not patentably distinct from each other because both applications are drawn to methods of treating HCV by administering pyrimidine 2'-methyl-ribofuranosyl nucleosides, optionally in combination with additional antiviral agents, using the same forms of compositions in the same patients. It is obvious that the instant application and the '443 application are substantially overlapping.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

It is noted applicants argued that since the only rejections left are provisional rejections, then the case should be issued according to MPEP 804, subsection I.B. However, since there are still pending rejections, this is not found persuasive.

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The provisional rejection of claims 130, 132-146, and 150-152 on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 2-17 and 19-68 of copending Application No. 11/005,444 is maintained for reasons of record. Although the conflicting claims are not identical, they are not patentably distinct from each other because both applications are drawn to methods of treating HCV by administering purine 2'-methyl-ribofuranosyl nucleosides and optionally in combination with another antiviral agent, using the same forms of compositions in the same patients. It is obvious that the instant application and the '444 application are substantially overlapping.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

It is noted applicants argued that since the only rejections left are provisional rejections, then the case should be issued according to MPEP 804, subsection I.B. However, since there are still pending rejections, this is not found persuasive.

The provisional rejection of claims 130-131 and 133-149 on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 2, 3, 8-17 and 19-57 of copending Application No. 11/005,446 is maintained for reasons of record. Newly added claims 158-160 are rejected for the same reasons. Although the conflicting claims are not identical, they are not patentably distinct from each other because both applications are drawn to methods of treating HCV by administering pyrimidine 2'-methyl-ribofuranosyl nucleosides, optionally in combination with additional antiviral agents, using the same forms of compositions in the same



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patients. It is obvious that the instant application and the '446 application are substantially overlapping.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

It is noted applicants argued that since the only rejections left are provisional rejections, then the case should be issued according to MPEP 804, subsection I.B. However, since there are still pending rejections, this is not found persuasive.

The rejection of claims 130-131 and 137-149 on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-32 of US Patent No. 6,812,219 is maintained for reasons of record. Newly added claims 158-160 are rejected for the same reasons. Although the conflicting claims are not identical, they are not patentably distinct from each other because both applications are drawn to methods of treating viruses from the Flaviviridae family (HCV in the instant application and flavivirus or pestivirus infections in the '219 patent) by administering pyrimidine 2'-methyl-ribofuranosyl nucleosides using the same forms of compositions in the same patients. It is obvious that the instant application and the '219 patent are substantially overlapping.

Applicants argue that the '219 patent is drawn to treating flavivirus or pestivirus infections, and the instant claims are drawn to treating HCV, which is not a flavivirus or pestivirus. This is not found convincing. The Flaviviridae virus family contains both flavivirus and HCV viruses, and it would be prima facie obvious to practice the invention of the '219 patent on another member of the Flaviviridae virus family, HCV. Applicants also argue that HCV belongs

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to a different genus than flavivirus and pestivirus, as HCV is a hepacivirus. The examiner does not dispute this, but notes that all three, flavivirus, pestivirus, and hepacivirus all belong to the family of viruses of Flaviviridae, and although the viruses belonging to the different genera have different biological properties and do not show serological cross-reactivity, great similarity in terms of virion morphology, genome organization, and presumed replication strategy have been noted. At the minimum, the examiner notes that it would be obvious to try a method of treating HCV in light of the references teaching to treat pestivirus and flavivirus infections with overlapping compounds. The Supreme Court in KSR noted that the analysis supporting a rejection under 35 U.S.C. 103 should be made explicit. The Court quoting *In re Kahn*, 441 F.3d 977, 988, 78 USPQ2d 1329, 1336 (Fed. Cir. 2006), stated that “[R]ejections on obviousness cannot be sustained by mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness.” KSR, 550 U.S. at \_\_\_, 82 USPQ2d at 1396. Exemplary rationales that may support a conclusion of obviousness include:

(E) “Obvious to try” – choosing from a finite number of identified, predictable solutions, with a reasonable expectation of success.

In the instant case, there is a finite number of genera within the Flaviviridae family, and a teaching that therapy against two of those members would afford the skilled artisan a reasonable expectation of success in practicing the instantly claimed method in light of that teaching.

Applicants also argue that the policy behind double patenting rejection is the prevention of an unjustified extension of the term of a patent, which does not support the examiners rejection in this case. However, the examiner agrees that the purpose of double patenting

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rejections is to prevent an unjustified extension of the term of a patent, however it is also appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969). As such, absent evidence to the contrary, the examiner believes the instant methods of treating HCV are obvious over the patent's claims to methods of treating flavivirus and pestivirus infections.

The rejection of claims 130, 132-146, and 150-152 on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-42 of US Patent No. 7,148,206 is maintained for reasons of record. Although the conflicting claims are not identical, they are not patentably distinct from each other because both applications are drawn to methods of treating viruses from the Flaviviridae family (HCV in the instant application and flavivirus or pestivirus infections in the '206 patent) by administering purine 2'-methyl-ribofuranosyl nucleosides and optionally in combination with another antiviral agent, using the same forms of compositions in the same patients. It is obvious that the instant application and the '206 patent are substantially overlapping.

Applicants argue the '206 patent and the instant application are not obvious the same as they argued the '219 patent and the instant application are not obvious as set forth supra. The examiner notes that it is believed they are obvious for the same reasons as above.

The rejection of claims 130-152 on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-18 of US Patent No. 7,105,493 is maintained for reasons of record. Newly added claims 158-160 are rejected for the same reasons. Although the conflicting claims are not identical, they are not patentably distinct from each other because both applications are drawn to methods of treating viruses from the Flaviviridae family (HCV in the instant application and flavivirus or pestivirus infections in the '493 patent) by administering purine and pyrimidine 2'-methyl-ribofuranosyl nucleosides and optionally in combination with another antiviral agent, using the same forms of compositions in the same patients. It would be obvious to use the method of treating a flavivirus in treating HCV, and visa-versa. It is obvious that the instant application and the '493 patent are substantially overlapping.

Applicants argue the '493 patent and the instant application are not obvious the same as they argued the '219 patent and the instant application are not obvious as set forth supra. The examiner notes that it is believed they are obvious for the same reasons as above.

### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to TRAVISS C. MCINTOSH III whose telephone number is (571)272-0657. The examiner can normally be reached on M-F 9:30-6:00.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shaojia A. Jiang can be reached on 571-272-0627. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Traviss McIntosh  
February 18, 2008  
Art Unit 1623

/Traviss C McIntosh III/  
Art Unit 1623